The opinion in support of the decision being entered today was *not* written for publication in and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ERIC G. LOVETT, ROBERT J. SWEENEY, DAVID T. JACOBSEN, and GILDO L. EPIS JR.

Appeal 2007-1451
Application 09/970,146
Technology Center 3700

Decided: June 13, 2007

Before WILLIAM F. PATE, III, LINDA E. HORNER, and ANTON W. FETTING, *Administrative Patent Judges.*

FETTING, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF CASE

This appeal involves claims 1, 3-10, 12-14, 16, 21-23, 26, 28-29, 33, and 58-69, the only claims pending and remaining under consideration in this application[1]. We have jurisdiction over the appeal pursuant to 35 U.S.C. §§ 6 and 134.

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[1] Claims 2, 11, 15, 17-20, 24-25, 27, 30-32, and 34-37 are withdrawn from consideration and claims 38-57 are cancelled.

We AFFIRM-IN-PART and ENTER A NEW GROUND OF REJECTION UNDER 37 C.F.R. § 41.50(b).

The Appellants invented a medical device that is controllable from an outside source, without having to implement invasive procedures, or without having to rely exclusively on additional instruments such as stylets. In addition, the stiffness of the medical device can also be modified at different portions and at different time periods which allows for the resistance of movement of the device in response to, for example, a beating heart (Specification 6:19-24). An understanding of the invention can be derived from a reading of exemplary claim 1, which is reproduced below.

> 1. A medical device comprising:
>
> a device body extending from a proximal end to a distal end;
>
> at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue; and
>
> a rheometric material electrically coupled with the at least one electrode, the rheometric material contracts and/or stiffens when electrical current is applied thereto.

This appeal arises from the Examiner's Final Rejection, mailed October 5, 2005. The Appellants filed an Appeal Brief in support of the appeal on April 20, 2006, and the Examiner mailed an Examiner's Answer to the Appeal Brief on July 13, 2006. A Reply Brief was filed on September 13, 2006.

PRIOR ART

The prior art references of record relied upon by the Examiner in rejecting the appealed claims are:

Maseda	US 6,514,237 B1	Feb. 4, 2003 (Nov. 6, 2000)
Lieber	US 4,329,993	May 18, 1982

REJECTIONS

Claims 1 and 3-8 stand rejected under 35 U.S.C. § 102(e) as anticipated by Maseda.

Claims 9-10, 12-14, 16, 21-23, 26, 28-29, 33, and 58-69 stand rejected under 35 U.S.C. § 103(a) as obvious over Lieber and Maseda.

ISSUES

With regard to the novelty rejection over Maseda, the Examiner finds that Maseda shows a device body that has conductive platinum metal discussed in col. 5, lines 1-19. The Examiner contends that this constitutes at least one electrode with the electroactive polymer representing the rheometric material electrically coupled to the electrode. The Examiner contends that the platinum is capable of transmitting and receiving electrical signals to and from tissue due to its conductive and biocompatible nature. (Answer 3). Thus, the Examiner is arguing that the device body itself acts as an electrode that has the capacity to transmit and receive electrical signals to and from tissue.

The Appellants contend that Maseda does not describe at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue (Br. 17-19). The Appellants are not particularly clear on the difference between the claim and the Examiner's characterization of Maseda, but their contention appears to focus on the lack of the claimed configuration so as to transmit and receive such signals. This focus is particularly clear in their contention of the lack of an inherent capacity in the electrode disclosed in Maseda to transmit and receive such signals (Br. 20).

With regard to the obviousness rejection over Lieber and Maseda, the Examiner finds that Lieber discloses a medical device comprising an elongate device body and at least one electrode 35 coupled thereto for stimulating and sensing. The Examiner finds that Lieber does not disclose the use of an assembly coupled with the device body including a rheometric material that contracts and/or stiffens when electrical current is applied thereto. To overcome this deficiency, the Examiner finds that Maseda teaches that the use of such an assembly on a wide range of medical devices including the type disclosed by Lieber is advantageous from the standpoint of increasing flexibility and steerability of the catheter as it is introduced into the body. The Examiner concludes that it would have been obvious to a person of ordinary skill in the art to have combined Maseda's rheometric material in Lieber's device because increased maneuverability through the tortuous vasculature system, high precision, and ease of placement, being very important design considerations for the medical artisan, make the incorporation of the Maseda assembly and related control system on the medical device of Lieber an obvious choice. (Answer 4).

The Appellants contend that combining Maseda with Lieber would impermissibly change the operation of Lieber (Br. 22-23), that there is no objective reason to combine Maseda with Lieber (Br. 23-24), and that the rejection fails to consider the claims as a whole (Br. 24-26).

Thus, the issues pertinent to this appeal are

- Whether the rejection of claims 1 and 3-8 under 35 U.S.C. § 102(e) as anticipated by Maseda is proper. In particular, the issue turns on whether the art applied shows at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue.
- Whether the rejection of claims 9-10, 12-14, 16, 21-23, 26, 28-29, 33, and 58-69 under 35 U.S.C. § 103(a) as obvious over Lieber and Maseda is proper. In particular, the issue turns on whether the teachings of Lieber and Maseda can be properly combined.

FACTS PERTINENT TO THE ISSUES

The following Findings of Fact (FF), supported by a preponderance of substantial evidence, are pertinent to the above issues.

Specification and Claim Terms

01. Rheometric material is a material that stiffens upon application of energy thereto (Specification 15:19-20).

Maseda

02. Maseda is directed toward medical devices, and more particularly to catheters, cannulae, guidewires, endoscopes and similar flexible probe devices incorporating electroactive polymers for increased maneuverability and controllability. (Maseda, col. 1, ll. 8-12).

03. The controllable intralumen medical device of Maseda integrates a controller and electroactive polymers with flexible probe medical devices such as catheters, guidewires, cannulae and endoscopes to create a device capable of navigating through tortuous passages where precise control of the device is desired. By configuring the electroactive polymer material (typically strands) in various schemes and synchronizing material activation via the controller, the potential movement of the flexible probe that can be achieved would essentially be limitless. The combination of strand length, placement in or on the flexible probe, size and level of activation will determine the amount and type of movement possible. For example, the device may be made to bend in any direction in three-dimensional space. In addition, specific movements or states of rigidity may be achieved. For example, the device may be made to wiggle, slither, twirl, pulse, vibrate, rotate, expand or virtually be made to make any other movement or combination of movements. The device may also be made rigid along its entire length or in sections such that it may be guided through difficult to pass regions such as regions having tight stenotic lesions. (Maseda, col. 2, ll. 41-62).

04. Maseda states:

> Ion-exchange polymer-noble metal composites are

> manufactured utilizing a chemical process in which a noble metal is deposited within the molecular network of the base ionic polymer. Metal ions, for example, platinum are dispersed throughout the hydrophilic regions of the polymer and subsequently chemically reduced to the corresponding metal atoms. This process results in the formation of dendritic-type *electrodes*. When an external voltage of approximately 2 volts or higher is applied to an ion-exchange polymer-noble metal composite film, it bends toward the anode. An increase in the applied voltage, up to a predetermined limit, causes a larger bending displacement. When the polarity of the voltage is changed, the film undergoes a swinging movement. The displacement of the film not only depends on the magnitude of the applied voltage, but also on the frequency of the applied voltage. Lower frequencies lead to higher displacements. Accordingly, the movement of the film or strip may be fully controllable by controlling the applied voltage.
>
> As stated above, strips or strands of ion-exchange polymer-noble metal composites *may be integrated into one or more sections of a flexible medical probe device*, for example, a balloon catheter. (Emphasis added) (Maseda, col. 5, ll. 1-23).

05. These portions of Maseda (FF 03 and 04) describe a flexible medical probe device, that the device is constructed with a material that contracts and/or stiffens when electrical current is applied thereto, which is the description of a rheometric material (FF 01), and that the device contains electrodes to route signals to the rheometric material for triggering the contraction and stiffening.

06. There is no contention that Maseda fails to show a rheometric material electrically coupled with the at least one electrode, the rheometric material contracting and/or stiffening when electrical current is applied thereto.

07. Maseda does not show an electrode disposed within the device that is configured to actually make contact with tissue and transmit and receive signals from the tissue to an electrical connector that is capable of transmitting the signals to an electronic measuring device.

08. Maseda states that one of the reasons for its invention is to overcome the concern with flexibility and steerability of coronary balloon catheter devices (Maseda, col. 1, ll. 14-33), and that its device can mimic the expansion of a balloon catheter device (col. 2, l. 63 – col. 3, l. 6).

Lieber

09. Lieber describes an invention that isolates the leads to electronic elements within a balloon catheter without requiring a separate lumen (Lieber, col. 1, ll. 62-66).

10. Lieber describes an electrode configured to transmit and receive cardiac signals, where the electrode is threaded through a catheter medical device (Lieber, col. 5, ll. 26-37).

11. The Appellants do not contend that Lieber's electrode is not an electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue.

12. Lieber describes its device containing the electrode as being a balloon catheter that uses a balloon to propel the inflated balloon-tipped catheter from the right atrium into the pulmonary artery (Lieber, col. 3, ll. 56-60).

13. The Appellants do not contend that any of the subject matter in claims 9-10, 12-14, 16, 21-23, 26, 28-29, 33, and 58-69 are not found in the combined teachings of Maseda and Lieber.

PRINCIPLES OF LAW

Claim Construction

The general rule is that terms in the claim are to be given their ordinary and accustomed meaning. *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989, 50 USPQ2d 1607, 1610 (Fed. Cir. 1999). In the USPTO, claims are construed giving their broadest reasonable interpretation.

> [T]he Board is required to use a different standard for construing claims than that used by district courts. We have held that it is error for the Board to "appl[y] the mode of claim interpretation that is used by courts in litigation, when interpreting the claims of issued patents in connection with determinations of infringement and validity." In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320 (Fed. Cir. 1989); accord In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023 (Fed. Cir. 1997) ("It would be inconsistent with the role assigned to the PTO in issuing a patent to require it to interpret claims in the same manner as judges who, post-issuance, operate under the assumption the patent is valid."). Instead, as we explained above, the PTO is obligated to give claims their broadest reasonable interpretation during examination.

In re Am. Acad. of Sci. Tech Ctr., 367 F.3d 1359, 1364, 70 U.S.P.Q.2d 1827, 1830 (Fed. Cir. 2004).

Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated

if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990).

Obviousness

A claimed invention is unpatentable if the differences between it and the prior art are "such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2000); *In re Kahn*, 441 F.3d 977, 985, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 13-14, (1966)). In *Graham*, the Court held that that the obviousness analysis begins with several basic factual inquiries: "[(1)] the scope and content of the prior art are to be determined; [(2)] differences between the prior art and the claims at issue are to be ascertained; and [(3)] the level of ordinary skill in the pertinent art resolved." 383 U.S. at 17. After ascertaining these facts, the obviousness of the invention is then determined "against th[e] background" of the *Graham* factors. *Id.* at 17-18.

The Supreme Court has provided guidelines for determining obviousness based on the Graham factors. *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007). "A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *Id* at 1731, 82 USPQ2d at 1396. "When a work is available in one field of endeavor, design

incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability." *Id.* For the same reason, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *id.* "Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id* at 1732, 82 USPQ2d at 1397.

ANALYSIS

Claims 1 and 3-8 rejected under 35 U.S.C. § 102(e) as anticipated by Maseda.

The Appellants contend that the claimed element of at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue is missing from Maseda. To reject a claim under novelty, all claimed subject matter must be shown, whether explicitly, implicitly, or inherently, in the single reference relied upon (*See Verdegaal, supra).*

Maseda shows the remaining subject matter of claim 1, and the Appellants do not contend otherwise (FF 01-06).

The Examiner contends that the device body itself is equivalent to the claimed electrode. The Examiner shows much creativity in applying known scientific facts regarding the conductivity of the platinum in the device body toward an argument of inherency. But, in the final analysis, the Examiner has not shown that the

device is actually configured to transmit and receive those signals, since such transmission must have some target, such as a medical measuring device. Maseda does not appear to show an example of an electrode used for such measurement, and therefore it is hardly surprising that Maseda fails to show any configuration to transmit and receive such signals (FF 07). Thus, we must agree with the Appellants that Maseda fails to show at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue.

Claims 9-10, 12-14, 16, 21-23, 26, 28-29, 33, and 58-69 rejected under 35 U.S.C. § 103(a) as obvious over Lieber and Maseda.

In contrast with the novelty rejection, the Appellants do not contend that any subject matter is missing from the combined teachings of Lieber and Maseda (FF 13), but only contend that that combining Maseda with Lieber would impermissibly change the operation of Lieber, that there is no objective reason to combine Maseda with Lieber, and that the rejection fails to consider the claims as a whole.

We first note that Lieber does indeed show the sole element that was lacking in Maseda for claim 1, i.e. the electrode (FF 10). We next note that although Lieber's device does provide navigation by a different method than Maseda, this method of navigation occurs in areas of heavy blood flow, such as in a cardiac chamber (FF 12), and Lieber does not state or even suggest that a balloon embodiment is required for Lieber's device to carry an electrode, or that it would be any less desirable to carry an electrode if an additional mechanism for positioning were provided as well.

On the other hand, as Lieber suggests the desirability of placing an electrode within a flexible device for the purpose of cardiac measurement (FF 09), Maseda describes the desirability of making a flexible device that travels within a body, such as Lieber's, more flexible and steerable (FF 08).

The Appellants contend that applying Maseda's teachings to Lieber would impermissibly change Lieber's principle of operation, citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). While *Ratti* held that a combination of references that would require a substantial reconstruction and redesign of the elements shown the prior art as well as a change in the basic principles under which the prior art was designed to operate is not a proper ground for an obviousness rejection, 270 F.2d at 813, 123 USPQ at 352, what *Ratti* was referring to was reconstruction and redesign of how all the elements interrelate in a manner relying on operational principles unforeseeable to a person of ordinary skill.

In *Ratti,* claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Its seal was incompressible and the device required rigidity for operation, whereas the claimed invention required resiliency.

But Lieber's electrode coupled with Maseda's device body does not do such violence to the operating principles of Lieber. Modifications by substitution, even if they omit the subject matter portion which a prior art patentee apparently regarded as his contribution to the art along with such advantages as it might

provide, where the modified apparatus is obvious in view of the prior art and where the retained portion of the subject matter will operate on the same principles as before, "are not authority for holding a rejection improper under such circumstances." *In re Umbarger*, 407 F.2d 425, 430-31, 160 USPQ 734, 738 (CCPA 1959), distinguishing *Ratti*. Thus, modifying Lieber by substituting a rheometric device body for the catheter still operates on the principle of Maseda, and the combination remains flexible and able to be guided for performing medical procedures, as needed in Lieber, Maseda, and the claimed invention.

Moreover, Lieber uses a balloon catheter for navigation in the heart (FF 12). Lieber's invention only goes to obviating the need for isolation of the leads to its electrode (FF 09). Maseda would provide an addition to, not a change to, Lieber's method of navigation. Further, Maseda specifically describes its application toward balloon catheters, such as Lieber's (FF 08).

The Appellants contend there is no motivation to combine Maseda with Lieber, but Maseda describes the advantages of its material in a device such as that in Lieber (FF 08). As to the claim as a whole, we note that applying Maseda's device housing to Lieber's electrode within such a device, provides the advantages taught by Maseda toward a device that must be navigated within a body, where the device contains the electrode whose need is taught by Lieber.

Thus, the Examiner has met the requirements of *Graham v. Deere* in finding that all of the claimed subject matter is described by Maseda and Lieber and that one of ordinary skill would have been led to combine those references to achieve the claimed subject matter.

NEW GROUND OF REJECTION

We enter a new ground of rejection under 35 U.S.C. § 103(a) of claims 1 and 3-8 as obvious over Lieber and Maseda.

ADDITIONAL FINDINGS OF FACT (FF)

We make the following additional enumerated findings of fact, which are supported by at least a preponderance of the evidence.

14. Maseda shows rheometric material is a strip of material wound around longitudinal device body (Maseda, col. 6, lines 4-7).

15. Maseda's rheometric material can be attached to the body in many configurations, such as in grooves on the body (Maseda, col. 5, ll. 56-67).

16. Maseda shows an elongate lead body configured to be coupled with an electrical instrument (Maseda, Fig. 1).

ANALYSIS

Claim 1 has substantially the same subject matter as claim 9, whose subject matter was found to be obvious over the combined teachings of Maseda and Lieber, *supra*.

As to claim 3, Maseda shows rheometric material is a strip of material wound around longitudinal device body (FF 14).

As to claim 4, Maseda shows its assembly comprising a rheometric material layer on the housing of the device (FF 04). Lieber's electrode is within the device housing and in contact with it, so the housing would be part of the outer surface of the electrode.

As to claim 5 and 6, Maseda's housing can be considered as divided arbitrarily into opposing portions, and since Maseda's rheometric material may be place in grooves along the body (FF15), at least one predictable way of aligning the grooves is so one strand or electrode is placed in a groove on one side of the catheter, while another strand or electrode is placed in a groove on the opposite side.

As to claim 7, the applicant is not claiming a pulse generator, but merely a lead body configured to be coupled to a pulse generator. Since Maseda shows an elongate lead body configured to be coupled with an electrical instrument (FF 16), such a connection would be capable of mating with a pulse generator, either directly or with appropriate adaptors.

As to claim 8, Maseda shows its rheometric material comprising an electroactive polymer (FF 04).

Thus, all of the subject matter of claim 1 and 3-8 are shown by the combined teachings of Lieber and Maseda. We have found that it would have been obvious to a person of ordinary skill in the art to have combined these teachings, *supra*.

CONCLUSIONS OF LAW

The Examiner has not shown that all of the claimed elements are found within Maseda. Accordingly we do not sustain the Examiner's rejection of claims 1 and 3-8 under 35 U.S.C. § 102(e) as anticipated by Maseda.

The Examiner has shown that all of the claimed elements are found within the combined teachings of Lieber and Maseda, and that those teachings are properly combined to achieve the claimed subject matter. Accordingly we sustain the Examiner's rejection of claims 9-10, 12-14, 16, 21-23, 26, 28-29, 33, and 58-69 under 35 U.S.C. § 103(a) as obvious over Lieber and Maseda.

We enter a new ground of rejection under 35 U.S.C. § 103(a) of claims 1 and 3-8 as obvious over Lieber and Maseda pursuant to 37 C.F.R. § 41.50(b).

DECISION

To summarize, our decision is as follows:

- The rejection of claims 1 and 3-8 under 35 U.S.C. § 102(e) as anticipated by Maseda is not sustained.
- The rejection of claims 9-10, 12-14, 16, 21-23, 26, 28-29, 33, and 58-69 under 35 U.S.C. § 103(a) as obvious over Lieber and Maseda is sustained.
- A new ground of rejection of claims 1 and 3-8 under 35 U.S.C. § 103(a) as obvious over Lieber and Maseda is made pursuant to 37 C.F.R. § 41.50(b).

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) (2006). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the appellant elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED-IN-PART

NEW GROUND OF REJECTION UNDER 37 C.F.R. § 41.50(b)

vsh

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